K073137

APR - 1 2008

510(k) Summary

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Date Prepared:	January 9, 2008
Trade Name:	GlucoSure Voice Blood Glucose Monitoring System
Classification:	Glucose test system, 21 CFR 862.1345, Class II
Product Codes:	CGA, NBW, JJX
Predicate Device:	GlucoTrack BGM, k062799
Device Description:	GlucoSure Voice consists of a meter, test strips, and control solutions for use in measuring blood glucose as an aid to monitor the effectiveness of diabetes control.
Intended Use:	The GlucoSure Voice Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Testing is done outside the body (*In Vitro* diagnostic use). The meter includes voice functionality to assist visually impaired users. It is indicated for both lay use by people with diabetes and in a clinical setting by healthcare professionals, as an aid to monitoring levels in Diabetes Mellitus. --- The Intended Use is the same as that as the predicate but with the addition of 1) Alternate Site Testing and 2) voice functionality.

510(k) Summary (continued)

Apex BioTechnology Corp.

GlucoSure Voice Blood Glucose Monitoring System

Functional and Safety Testing:	Clinical testing was done with persons with diabetes to verify proper performance for fingerstick and Alternate Site Testing (AST) using palm and forearm blood sampling. Professional fingertip meter results were compared with AST results collected both by professionals and by persons with diabetes. Data were analyzed by linear regression analysis, Clarke Error Grid analysis and bias analysis. Results met pass/fail performance criteria. The clinical evaluation included testing of the voice functionality with visually impaired persons with diabetes. Non-clinical testing of precision, linearity, and temperature and humidity effects was also conducted.
Conclusion:	The modification to the original device (adding voice functionality) and to the Intended Use (adding AST sampling) does not adversely affect performance and the modified device is substantially equivalent to the unmodified predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Apex Biotechnology Corp.
c/o Mr. Thomas Shen
Chairman & CEO
No. 7, Li-Hsin Road V
Hsinchu Science Park
Hsinchu, Taiwan, R.O.C. 30078

APR - 1 2008

Re: k073137
Trade Name: GlucoSure Voice Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Monitoring System
Regulatory Class: Class II
Product Codes: NBW, CGA, JJX
Dated: February 04, 2008
Received: February 15, 2008

Dear Mr. Shen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: k073137

Device Name: GlucoSure Voice Blood Glucose Monitoring System

Indications For Use:

The GlucoSure Voice Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Testing is done outside the body (*In Vitro* diagnostic use). The meter includes voice functionality to assist visually impaired users. It is indicated for both lay use by people with diabetes and in a clinical setting by healthcare professionals, as an aid to monitoring levels in Diabetes Mellitus.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ____X____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

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...ce of In Vitro Diagnostic Device
...ation and Safety

K073137

Indications for Use Statement

510(k) Number: k073137

Device Name: Contrex Plus Glucose Control Solution

(Part of the GlucoSure Voice Blood Glucose Monitoring System)

Indications For Use:

The purpose of the control solution test is to validate the performance of the Blood Glucose Monitoring system using a testing solution with a known range of glucose. A control test that falls within the acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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